

We are IntechOpen, the world's leading publisher of Open Access books Built by scientists, for scientists

4,800

Open access books available

122,000

International authors and editors

135M

Downloads

Our authors are among the

154

Countries delivered to

TOP 1%

most cited scientists

12.2%

Contributors from top 500 universities



WEB OF SCIENCE™

Selection of our books indexed in the Book Citation Index
in Web of Science™ Core Collection (BKCI)

Interested in publishing with us?
Contact book.department@intechopen.com

Numbers displayed above are based on latest data collected.
For more information visit www.intechopen.com



Implementation and Management of Strategies to Set and to Achieve Clinical Targets

Bernard Canaud, Ciro Tetta, Daniele Marcelli,
Guido Giordana, Stefano Stuard, Katrin Koehler,
Flavio Mari, Carlo Barbieri, Miryana Dobрева,
Andrea Stopper and Emanuele Gatti

Additional information is available at the end of the chapter

<http://dx.doi.org/10.5772/53041>

1. Introduction

Today health care and care provider organizations are facing new challenges. They must continually improve their services to provide the highest quality at the lowest cost. Pressures to increase the quality and lower the costs are coming from accreditation and certification boards, public health authorities and the media that publish comparisons and rank facilities by performance. In addition, new demands on health care systems require action accountability with hard outcome data based on morbidity and mortality. Quality control, quality assurance and continuous quality improvement (CQI) processes derived from the manufacturing and industrial world have been progressively applied with success to medicine and in particular to the treatment of end stage renal disease.

[1,2]. It is generally accepted that quality control describes the process for reviewing and checking that targets according to whether a defined set of criteria has been achieved, while quality assurance is the process in which systematic monitoring, collecting and evaluating the performance of a facility or a care network are assessed to ensure that standards of care are met [3]. CQI describes the action that takes place after analyzing outcomes with the intent of improving the results and reducing variation from the target. In this respect, renal replacement therapy by dialysis represents a particular field of application where quality control and quality assurance processes have been shown to be very efficient tools for optimizing treatment adequacy and improving patient outcomes.

Over the last ten years, it has been well documented that survival and outcomes of stage 5 chronic kidney disease patients on dialysis are depending on age, comorbid status at the start of treatment, but also on quality care and practice patterns [4,5,6]. Renal replacement therapy by dialysis is a clear paradigm where results are quite closely tied to quality assurance and CQI processes. Dialysis adequacy is a multi-target concept developed to face complexity of uraemia disorders and to provide physicians with an easy tool based on a 'checklist' to address the patients' vital metabolic needs. Dialysis prescription and adjunctive medical treatment are intended to provide over time (from years to decades) an adequate and regular correction of metabolic disorders to each patient, to prevent side-effects and 'un-physiology' of intermittent dialysis and to preserve quality of life at an affordable cost. Treatment adequacy is then closely tied to the quality assurance process that links prescription and treatment delivery [7]. On one hand, prescription of the haemodialysis treatment relies mainly on the patient's metabolic needs, cardiovascular and general tolerance of sessions, dietary compliance, residual renal function [8] and local health care and economic offer. It is not our intent to revisit here the principle of prescribing dialysis but just to remind that it relies on five primary elements: dialysis modality (haemodialysis, haemodiafiltration, ect), dialyzer type, total weekly treatment duration (number of sessions per week and duration of session), blood flow and 'dry weight' achievement. Additional components need to be considered as secondary part of the prescription being part of the prescription such as dialysate flow, substitution flow in convective therapies, dialysate electrolytic composition, antithrombotic drugs, specific medications (iron, erythropoiesis-stimulating agents, vitamins ect) [9]. On the other hand, adequate delivery of haemodialysis relies on the continuous achievement of pre-specified targets using quality control markers intended to monitor major metabolic disorders of the uraemic syndrome. The markers clearly identified and recommended by international best practice guidelines (formerly the European Best Practice Guidelines, EBPG, now the European Renal Best Practice, ERBP, KDOKI at <http://www.european-renal-best-practice.org/>, the National Kidney Foundation Kidney Disease Outcomes Quality Initiative, NKF KDOQI, Kidney Disease: Improving Global Outcomes, KDIGO) are summarized in clinical performance measures (CPM) covering 10 main domains: 1.[7]; 1. Lack of clinical uraemic symptoms; 2. Fluid volume control; 3. Blood pressure control; 4. Adequate dialysis dose delivery (small and middle molecules); 5. Acidosis correction; 6. HyperkalemiaHyperkalemia control; 7. Divalent ion metabolism (phosphatemia, calcaemia and magnesaemia); 8. Iron repletion and anaemia correction; 9. Prevention of malnutrition; 10. Prevention of inflammation and oxidative stress. As shown by the international Dialysis Outcome Practice Patterns (DOPPS) study, clinical practices should be now considered as a major component of quality of care having a direct impact on dialysis patient outcomes. By linking country and unit, specific practices to patient outcomes, the DOPPS study introduced a new dimension in the control of the overall quality of care of haemodialysis patients. Among the main findings of DOPPS it must be stressed that less use of central venous catheter [10,11], longer duration of dialysis with reduced ultrafiltration rate [12], adequate dialysis schedule [13], higher dialysis dose delivered [14], better control of fluid overload and blood pressure control [15], prevention of metabolic bone disease [16,17], better control of anaemia with lower erythropoiesis-stimulating agent dose require-

ment [18,19], enhanced convective dose [20] are all beneficial to patient outcomes. In addition, DOPPS has also shown that overall clinical practices at the facility level were essential for improving patient outcomes [21]. In other words, dialysis facilities achieving optimal targets for a core of selected quality control items in the majority of patients were extending life expectancy to each patient individually [21]). In this new perspective, it is then necessary to implement complementary items of quality control probing the degree of compliance of dialysis facilities with best clinical practices [22,23]. A quality control tool in this case may be simply expressed as the percentage of patients within the predefined target range per unit. Combining clinical performance measures and percentage of patients complying with targeted objectives, a new key performance indicators (KPI) may be elaborated for a group of patients treated either within a dialysis unit and/or within a network. In addition to directly addressing clinical practices and patient outcomes, DOPPS has been used as a platform for economic and policy analyses [24]. Fresenius Medical Care as the world's largest integrated provider of products and services for individuals undergoing dialysis because of chronic kidney failure was historically involved in the development of continuous quality improvement processes of dialysis care. We take this opportunity to present additional results collected within the Fresenius Medical Care network system (EuCliD, European Clinical Database). In this article, we discuss some practical ways of implementing the CQI process based on real time collection of clinical performance measures and KPI. Using selected indicators we explore the beneficial effects over time of achieving targeted criteria of good medical practice in terms of patient outcome and cost saving effect. In developed countries, health care costs are currently progressively increasing and in case of U.S. exceeds 17% of the Gross Domestic Product (GDP). Other countries spend less of their GDP on health care but demonstrate the same increasing trend.

Today, national health care systems worldwide are expected to deliver more and better services to a greater number of patients, while dealing with ever more reduced economical resources on the one hand and increased costs on the other hand. Major challenges posed to healthcare systems include global ageing and increase in so-called civilization diseases, growing budget deficits and slowing economic growth, worldwide health care workers shortage and commodity shortage. The need to provide innovative and high-quality, innovative products and treatments should able to contribute to improving outcomes and to be in balance with new perspectives addressing the health care change. Innovation has to contribute to solving the challenge of the economic pressure, though innovation will need standardization according to the rules of good clinical practice and proved by evidence-based medicine. Perverted incentives may also contribute to rising costs as well as reimbursement as providers are reimbursed for performed procedures rather than achieved ones. Moreover, a common weakness of health care systems is linked to the low level of responsibility for the costs generated by the patients at the time they require the medical service. The costs for renal replacement therapy is exceedingly high and are consuming a significant proportion of health care budgets. The global prevalence of kidney failure continues to rise, and treatment is costly; thus, the burden of illness is growing and the resources allocated to treatment are increasing. According to the U.S. Renal Data System (USRDS) Annual Report 2011, total Medicare costs in 2009 rose 8%, to \$491 billion; costs for ESRD rose

Medical Care in Europe, coordinates the clinics in Europe, Middle East, Africa and Latin America, that use state-of-the-art dialysis products, renal pharmaceuticals and therapies (all of which are constantly being improved), as well as care from qualified, motivated clinic personnel who regularly participate in training programs. In every country of its European network, NephroCare adapts its care model to reflect the national health care architecture and to further develop concepts within the predefined regulatory frame [29]. To impact the quality and efficacy of a health care service, patient and cost related information must be captured, updated, and shared with all stakeholders in a timely and effective manner to not only ensure universal access to quality data, but also to extend essential information to key clinical decision makers [30]. The Balanced Scorecard tool has allowed NephroCare to promote the collaboration between public institutions and the private provider in more than 20 European countries, giving in the hands of the public a way to control the quality outcomes achieved in the clinics [31,29]. This has been an important achievement for quality in the European healthcare context where dialysis is still mainly provided by public hospitals. It has to be noted that all this would not be possible without the implementation of the electronic medical record EMR). Like in the rest of the health care context, the use of a specialized software to keep track of the patients' medical history has made it possible for the nephrologist to have immediate access to an enormous amount of patient information. In the last few years, a large number of software platforms have been proposed and some of them offer personalized versions, which could be customised to the needs of the nephrologist (The DoctorsPartner Nephrology EMR, by DoctorPartner LLC ectectect).

2. The Electronic Medical Record (EMR): Benefits of the worldwide web, quick and simple data collection and analysis, statistics as a tool to predict outcomes

Paper-based records are still by far the most common method of recording patient information for most hospitals and practices in the world. A critical aspect of paper-based records is legibility. Handwritten paper medical records can be associated with poor legibility, which can contribute to medical errors [32]. Pre-printed forms, the standardization of abbreviations, and standards for penmanship were encouraged to improve reliability of paper medical records. The majority of physicians still find it easier to handle paper-based records and consider entry of data into an EMR tedious. However, paper-based data require a significant amount of storage space and to retrieve information is quite difficult and time-consuming [2]. This is particularly true in the case of person-centred records, which are impractical to maintain if not electronic. For this reason, retrospective analysis based on large historical case series and programs based on data, as Continuous Quality Improvement, are only recently becoming popular with the deployment of EMR. Because of these many "after entry" benefits, governments, insurance companies and large medical institutions are heavily promoting the adoption of EMR. The benefits can be especially high considering the different uses of the same information, i.e. for monitoring a patient, CQI requirements, for reporting purposes or for billing a service. A critical aspect of EMR is the codification of information.

In human communication, free text is the natural approach used not only for oral communication but also for written medical records. Free text offers the option to maximize the benefit of a given language to describe situations well, but it may be difficult to maintain the same content once translated into another language. Additionally, it cannot be used for statistical purposes. Codification is somehow universal, and a code is a kind of ideogramme readable by people of different languages. To get more out of an EMR, information has to be codified as much as possible, allowing an easier use. In general electronic records help with the standardization of forms, terminology and abbreviations, and data input. However, the increased portability and accessibility of electronic medical records may also increase the risk of unauthorized access and theft by as acknowledged by increased security requirements. The ability to exchange records between different EMR systems ("interoperability") facilitates the co-ordination of health care delivery in non-affiliated health care practices. Nowadays it is very common to see primary physicians working with computerized systems in their practice. However, very often they use systems which could be described as minimally functional since they include only orders for prescriptions, orders for tests, viewing laboratory or imaging results, and clinical notes. A more sophisticated use, including further analytical elaboration of the data as required by the CQI approach, is normally not part of the routine. To ensure the quality of care delivered to patients treated in its dialysis units, Fresenius Medical Care continuously monitors its dialysis services. The overall quality management system of the company, which is based on CQI, provides the necessary framework. CQI programs, incorporating the implementation of clinical practice guidelines and CPM by dialysis providers, demand the development of computerized monitoring systems in order to collect and supply information on the dialysis treatment. Therefore, Fresenius Medical Care developed a specific clinical database as a tool to monitor critical aspects of dialysis care and improve the quality of care.. This central database is called EuCliD, the acronym for European Clinical Database as the database was first developed in Europe. EuCliD collects the most-important medical information on the treatment of dialysis patients. The data provide a basis for clinical trials and help improve the treatment of dialysis patients by comparing the different treatments. The description of the first version of the database has already been published [33]. Right from the outset, EuCliD was structured to follow a logical information flow. During the last years the software has been updated and a new project based on an enlarged scope has been initiated. EuCliD 5 now includes daily treatments performed throughout European, Latin American and African Countries. The new project was aimed not only at supporting quality assurance, but also to facilitate the day-to-day work of the clinical staff. As a result, EuCliD 5, is a multilingual and fully codified software using, as much as possible, international standard coding tables (ICD10, WHO: International Statistical Classification of Diseases and Related Health Problems 1992; ISCED, UNESCO, 1997;ISCO-88, International Standard Classification of Occupations 1988 etc.). EuCliD 5 collects and handles sensitive medical patient data, and ensures the confidentiality of these data [34]. EuCliD 5 has been approved by the respective national or regional authorities prior to data entry and the initiation of data transfer. Of course, the transfer of private patient data out of the dialysis center is not permitted. The availability of EuCliD 5 data, as well as the increasing interoperability of data present in other systems has allowed

the practical implementation in a clinical environment of tools like the Balanced Scorecard, a tool developed in the scientific domain of complex system management. Key characteristic of Balanced Scorecard is the aim of maximizing concurrent interests of different stakeholders in a balanced form, concentrating on KPIs able to describe variables whose improvement can improve the overall system behavior [29,30]. Each KPI is not a reported value only, but much more the headline of a project or program to improve performance in a strategic relevant, target oriented way. KPIs are dynamic and when they approach saturation need to be substituted by new ones in a continuous development process of quality improvement and know-how and operational excellence. Related to the use of a Balanced Scorecard, there are certain *caveat* to consider: since the Balanced Scorecard is nothing else than a model of stage 5 chronic kidney disease management, Wrong or inadequate model design and definition and wrong or inadequate implementation (or execution) can lead to erroneous conclusions. In this sense the right selection of KPI and the appropriateness of the derived actions are of crucial importance as well as the validation of data and their causal relationships with outcomes. It is fundamental to understand how to manage and not just measure performance and this will not happen without regular review sessions at all levels.

3. Self-organizing maps for continuous quality improvement

In order to derive improvements from the clinical data Self-Organizing Maps (SOMs), an innovative approach recently introduced by Fresenius Medical Care, could complement standard statistical methods used to extrapolate information. A brief description of SOMs follows: As an example, let us consider a dataset containing the values of four variables (Weight, Height, Body Mass Index – BMI –, and Fat) for 251 patients, for which we built a SOM with 84 neurons (Fig. 1). In this case, each neuron is characterized by a vector of four elements, one for each variable: each neuron can be seen as an “average patient”, whose height is the average height of all patients associated with that neuron, and the same goes for the other three variables. Neurons that are close in the SOM represent patients that are similar from the point of view of the considered variables. Once the SOM has been configured, different effective views of the distribution of the data can be obtained. In particular, one can focus on a specific variable of the input data by color-coding each neuron of the SOM based on the value of that variable. This kind of plot is called component plane of the SOM (see, for instance, Fig. 1). By comparing different planes (i.e., different variables) it is possible to identify relations existing among the variables. Notice that each given neuron (depicted in Fig. 1 as a hexagon) always represents the same subset of data, over all the different component planes. For example, in Fig. 1 it can be noticed that the same units in the top left of the four component planes represent patients with large weight, medium to small height, large BMI, and large percentage of fat. The units in the bottom right of the graph represent patients with small weight, medium to small height, small BMI, and small percentage of fat. It should be noted that, although the SOM algorithm is not aware of how the BMI is computed, the relation between height and weight that determines the BMI clearly emerges

from the component planes. This example shows how the SOM can be effectively used to extract the relations among the variables of interest.

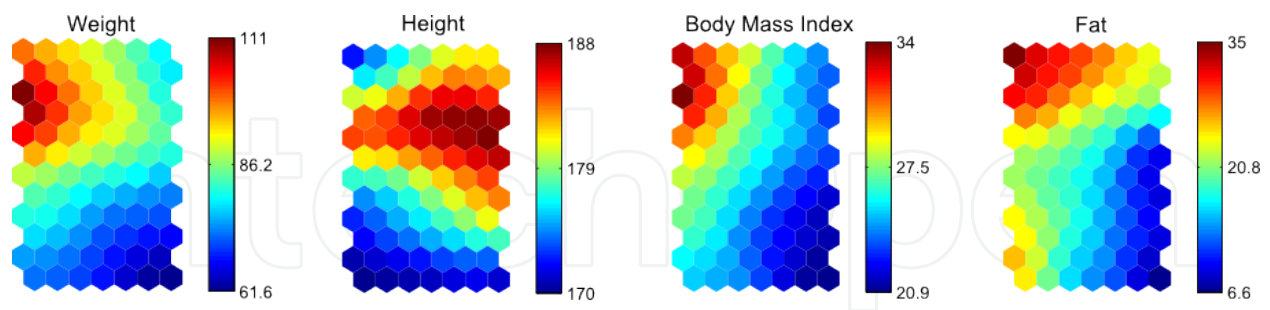


Figure 1. Example of SOMs of different variables (Weight, Height, Body Mass Index – BMI –, and Fat) for 251 patients.

To ensure the implementation of CQI policies, extensive data collection from the care units, and their reassembly into meaningful performance indexes need to be put in place. Such processes generate massive amounts of data, which carry information that is not always easily extracted by means of standard statistical approaches. On the other hand, the wealth of the available data allows the application of machine learning approaches, which are able to find structure in complex datasets, even in the absence of an a priori hypothesis about what should be looked for. In other words, the data-driven approach of such techniques *lets the data speak for themselves*, allowing interesting, possibly unanticipated information to emerge. In turn, such information can be used by the management to discover areas of excellence, or clinics where a margin for improvement exists, as well as strategies for achieving such improvement. In the context of the Balanced Scorecard, the available data are organized as vectors of KPI scores, one per clinic-month. Given these data, it is of particular interest to extract the relations existing among different KPIs for particular groups of clinics, in order to identify clusters that share a similar performance pattern, as characterized by correlated scores on specific KPIs.

For this reason, we have recently introduced the use of SOMs to analyze BSC data [34]. SOMs have already been validated as reliable tools in health care, for instance for population studies [35](Basara H, Yuan M, 2008) and for organization [36] or economic evaluations [37]. A Self-Organizing Map is a machine learning paradigm mainly used for clustering and visualization of data in high dimensional spaces (ie, data with a large number of variables) [38]. The SOM model is composed of units, often referred to as *neurons*, organized in a low dimensional reticular structure (generally in bi-dimensional or tri-dimensional space), which act as prototypes of the input data in such lower-dimensional space. The SOM learns in an *unsupervised* way to assign each input data point to the neuron that is most similar to it, by means of a training procedure that aims at preserving the topological characteristics of the input space – that is, similar input vectors are mapped to close regions in the SOM. Once the SOM has been configured, different effective views of the distribution of the data can be obtained. In particular, one can focus on a specific dimension of the input vectors (in our case, one specific KPI) by colour-coding each neuron of the SOM based on the value that the

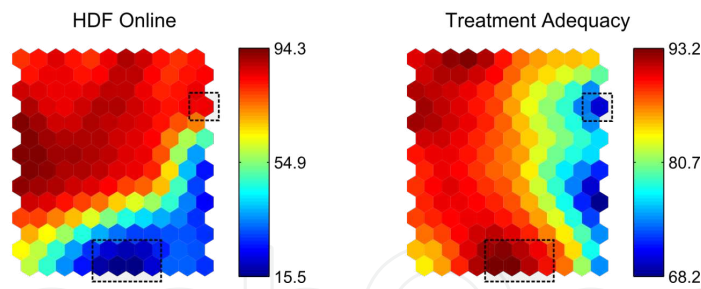


Figure 2. Two component planes (relative to the HDF online KPI and to the Treatment Adequacy KPI, respectively) of an SOM trained on BSC data from Portuguese clinics of the NC network. The dashed rectangles superimposed on the planes indicate regions of the SOM where interesting groups of clinics can be found (see discussion in the text). SOM training and visualization were performed in MATLAB using the SOM toolbox [39]. The SOM is shown as a collection of neurons (hexagons) placed in a two-dimensional grid, where the focus is on the relative, rather than the absolute, position of each neuron: that is, the main information content lies in the neighborhood relationships among neurons, as adjacent neurons contain similar KPI records. We can therefore compute the average score for a given KPI in each neuron: this is represented by a color code (colorbar shown on the right) in the component plane relative to that KPI

prototype takes on that particular dimension. This kind of plot is called *component plane* of the SOM (Fig. 2).

Many interesting insights can be achieved when running an SOM-based analysis on BSC data. For instance, Fig. 2 shows two component planes obtained from an SOM trained on the BSC data of Portuguese clinics (33 clinics, monitored for 28 months, from January 2008 to March 2010). By comparing different planes (*i.e.*, different KPIs), it is possible to identify groups of data (in our case, clinic-month KPI vectors) that share a similar pattern of performance (as they are located in the same region of the map) and characterize such patterns in terms of specific KPI relations. Thus, for instance in Fig. 2, all KPI vectors that are assigned to the upper left corner of the SOM share a similar structure, which is characterized, among other things, by a high score both on the HDF Online and the Treatment Adequacy KPIs (positive correlation). From these planes one can notice that, while these two KPIs are positively correlated for most clinics in the dataset, there are also cases where treatment adequacy is low (see marked unit on the right side of the map), and cases where a good treatment adequacy is achieved (bottom part of the map). These groups of clinics thus show an interesting performance pattern that might prompt further investigations, and possibly corrective measures. To this end, one can easily trace back the clinics falling into these regions of the map to retrieve all relevant information about them. Similarly, in Fig. 3, two different component planes from the same SOM as above are shown: as expected, the patient growth and new patient inflow KPIs are, in general, directly correlated. However, it is also possible to identify groups of clinics that show a moderately high new patient inflow while maintaining a low patient growth score (upper left corner).

This observation can allow to quickly identifying those clinics where, presumably, there is a relevant outflow of patients and, therefore, there might be the need for corrective measures. As a final example, consider Fig. 4 where two component planes of a different SOM, trained on data from Turkey (46 clinics monitored during the same period as those in Portugal), are shown.